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4A 510(k) Summary

510(k) Summary

Date Prepared	26 Jul, 2013
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Device name	EasyCare Online
Product codes	73 MNS 73 MNR
Classification reference	Ventilator, Continuous, Non-Life-Supporting (21 CFR 868.5895, Product Code 73 MNS) Breathing Frequency Monitor (21CFR 868.2375 product code 73 MNR)
Predicate device(s)	EasyCare Online (510(k) number (K123557) ApneaLink Plus (510(k) number (K083575)
Reason for submission	Expanded Intended for Use.

Intended Use

EasyCare Online is a web based solution for healthcare specialists intended to:

- assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded by an EasyCare Online compatible home sleep test device.
- transfer and display, usage and therapeutic information that has been transmitted remotely from the patient's therapy device located in the home. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device for the treatment of obstructive sleep apnea or respiratory insufficiency. EasyCare Online also provides remote settings capabilities

Device Description

EasyCare Online is a web application that can transfer, store, manage and display usage and therapy data from (ResMed compatible flow generators) and diagnostic data from (ResMed compatible sleep study devices). The data is transferred from the device either wirelessly through a communications module, or with the aid of an SD card and internet technology, to a central database and then displayed on the clinician's/DME's computer, through a web based application such as Internet Explorer.

EasyCare Online is used to monitor and optimize the therapy of patients diagnosed with sleep apnea or respiratory insufficiency, who are using a ResMed therapy device or home sleep test study device. The application enables patient usage data to be shared across several different user groups for the primary purpose of monitoring patient compliance and home sleep studies. Clinical users, Home Medical Equipment (DME) providers and other healthcare specialists can access data with ResMed approved user accounts. Also, clinical users and DMEs are able to address any clinical issues in a timely manner and provide the necessary patient support, including the modification of device settings. EasyCare Online supports physicians in the diagnosis Sleep Disordered Breathing, by reviewing home sleep test results via their web browser or download the clinical data to their PC for further analysis.

Basis for Determination of Substantial Equivalence

The modified EasyCare Online has the following similarities to the previously cleared predicated device:

- Similar intended use
- Same operating principle
- Same technology
- Same manufacturing (deployment) process

EasyCare Online modifications provide additional features for collection, storage and reporting of respiratory nasal airflow, respiratory effort, pulse rate and oxygen saturation during sleep studies which is used to assist the physician in diagnosis sleep disordered breathing. The physician prescribed device will help to recognize sleep-related respiratory disorders and lead to comprehensive clinical diagnosis and therapy.

With the ApneaLink Plus (also referred to as ApneaLink to Cloud – ALC) Software integration with EasyCare Online, a regression analysis showed that minimal affect on the existing system would occur. Confidence system level testing was conducted to ensure integration of ALC was conducted and found not to change the performance of EasyCare Online. Accordingly, 73 MNS and 73 MNR ResMed compatible devices function correctly with EasyCare Online. These changes do not affect the safety and efficacy of the device, as the EasyCare Online uses the existing data types and communications mechanisms between therapy devices as supported by the predicate device (K123557).

Feature	EasyCare Online [Primary predicate(K123557)]	ApneaLink Plus [Secondary predicate(K083575)]	EasyCare Online (modified)	Comments
Intended Use	EasyCare Online transfers and displays to physicians, usage and therapeutic information that has been transmitted remotely from the patient's flow generator located in the home. EasyCare Online also provides remote settings capabilities. EasyCare Online is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed flow generator for the treatment of obstructive sleep apnea or respiratory insufficiency	The ApneaLink Plus device is indicated for use by Health Care Professionals(HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation.	EasyCare Online is a web based solution for healthcare specialists intended to: • assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded by an EasyCare Online compatible home sleep test device. • transfer and display, usage and therapeutic information that has been transmitted remotely from the patient's therapy device located in the home. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device for the treatment of obstructive sleep apnea or respiratory insufficiency. EasyCare Online also provides remote settings capabilities	Equivalent *Combined and simplified-same intent.*
Functionality	• Centralised database • Compliance reports • Therapy reports. • Settings management • Patient management	• Diagnostic Home Sleep Test Reports (HSTR)	• Centralised database • Compliance reports • Therapy reports. • Settings management • Patient management • Diagnostic Home Sleep Test Reports (HSTR)	Equivalent *Combined features*
Data transfer Technology	• Wireless • SD Card/Internet	USB connection from ApneaLink Plus to the Personal Computer	• Wireless • SD Card/Internet • File upload/Internet	Equivalent

Feature	EasyCare Online [Primary predicate(K123557)]	ApneaLink Plus [Secondary predicate(K083575)]	EasyCare Online (modified)	Comments
Therapy settings	• Pressure • Mode • Comfort	—	• Pressure • Mode • Comfort	Equivalent
Patient information	• Mask Leak • AHI • Prescription Pressure • Start Pressure • Minute Ventilation • Respiratory rate • Mode • EPR Level • Pressure Support Level	—	• Mask Leak • AHI • Prescription Pressure • Start Pressure • Minute Ventilation • Respiratory rate • Mode • EPR Level • Pressure Support Level	Equivalent
Home Sleep Test Information (HSTI)	—	• Recording times • Event statistics (including AHI, apnea index, hypopnea index, apnea classification) • Oxy statistics (ODI, oxygen saturation) • Pulse statistics • Breath statistics	• Recording times • Event statistics (including AHI, apnea index, hypopnea index, apnea classification) • Oxy statistics (ODI, oxygen saturation) • Pulse statistics • Breath statistics	Equivalent Side by side testing of ECO (modified) and ApneaLink Plus PC software demonstrated that ECO correctly and accurately displayed home sleep test data belonging to ApneaLink Plus devices.

Non Clinical Testing

Design and non-clinical verification activities were performed on EasyCare Online as a result of the updated risk analysis and design requirements. Verification testing included end-to-end testing to verify data transfer integrity between end user browser PC and EasyCare Online was successfully implemented. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that new version of EasyCare Online is substantially equivalent to the predicate device, EasyCare Online (K123557).

Side-by-Side testing using the same data showed that both the predicate device ApneaLink Plus (K083575) and EasyCare Online produced the same home sleep test data. EasyCare Online met the predetermined pass/fail criteria.

Testing	Scope of testing	Result
Software verification	Regression and End-to-End system testing was conducted to confirm that changes introduced in the code did not impact on previous ECO functionality (K123557) and verify the addition of ApneaLink Plus (K083575) functionality into ECO.	PASS
Side-by-side testing	Three patient breathing pattern scripts were used for side by side testing of ECO (modified) and ApneaLink Plus PC software ((K083575) to verify that ECO correctly and accurately displayed home sleep test data belonging to ApneaLink Plus devices.	PASS

Clinical Testing

No clinical testing is required for EasyCare Online.

Conclusion

The modified version of EasyCare Online is substantially equivalent to the predicate device, EasyCare Online (K123557)

The modified version of EasyCare Online is as safe and as effective, and performs substantially equivalent to the predicate devices, EasyCare Online (K123557) and ApneaLink Plus (K083575).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Resmed Corporation
Jim Cassi
Vice President, Quality Assurance Americas
9001 Spectrum Center Blvd.
SAN DIEGO, CA 92123

Re: K132371
Trade Name: EasyCare Online
Regulatory Class: III
Product Code: MNS
Dated: October 16, 2013
Received: October 21, 2013

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

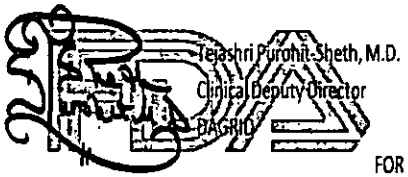
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin Keith
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132371

Device Name
EasyCare Online

Indications for Use *(Describe)*

EasyCare Online is a web based solution for healthcare specialists intended to:
• assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded by an EasyCare Online compatible home sleep test device.
• transfer and display, usage and therapeutic information that has been transmitted remotely from the patient's therapy device located in the home. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device for the treatment of obstructive sleep apnea or respiratory insufficiency. EasyCare Online also provides remote settings capabilities

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S

FDA Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.11.20 15:25:31 -05'00'